

Amendment

The following listing of claims replaces all prior versions and listings in the application:

Listing of Claims

1-32 (Canceled).

33. (Currently Amended) A bi-layer wax-film composite ~~comprised of~~ comprising a pH-sensitive mucoadhesive layer ~~and bonded to~~ a water-insoluble wax layer, the bi-layer wax-film composite having a total thickness of less than 5 mm.

34. (Original) The wax-film composite of claim 33, wherein the pH-sensitive mucoadhesive layer is present at a concentration of 20% to 90% by weight, and the water-insoluble wax layer is present at a concentration of 10% to 80% by weight.

35. (Currently Amended) The wax-film composite of claim 33, wherein said pH-sensitive mucoadhesive layer comprises ~~is comprised of~~:

- at least one water-insoluble swellable mucoadhesive polymer,
- at least one pH-sensitive film-forming polymer, and
- at least one molecule of interest.

36. (Previously Presented) The wax-film composite of claim 35, wherein the water-insoluble swellable mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

37. (Previously Presented) The wax-film composite of claim 35, wherein the water-insoluble swellable mucoadhesive polymer is Noveon or Carbomer.

38. (Previously Presented) The wax-film composite of claim 35, wherein the water-insoluble swellable mucoadhesive polymer is present in the pH-sensitive mucoadhesive layer at a concentration from 0.1% to 20% by weight.

39. (Previously Presented) The wax-film composite of claim 35, wherein the pH-sensitive film-forming polymer present in the pH-sensitive mucoadhesive layer is a copolymer of methacrylic acid and acrylic or methacrylic ester.

40. (Previously Presented) The wax-film composite of claim 35, wherein the pH-sensitive film-forming polymer is present in the pH-sensitive mucoadhesive layer at a concentration from 0.05% to 10% by weight.

41. (Previously Presented) The wax-film composite of claim 35, wherein the pH-sensitive film-forming polymer present in the pH-sensitive mucoadhesive layer is a Eudragit polymer, or chemical derivative thereof.

42. (Original) The wax-film composite of claim 33, wherein the water-insoluble wax layer comprises at least one water-insoluble pharmaceutical wax having a melting point between 40° C and 100° C and at least one water-soluble or water-swellaable polymer.

43. (Original) The water-insoluble pharmaceutical wax of claim 42, wherein said wax is DENTSPLY® Utility Wax, beeswax, emulsifying wax, microcrystalline wax, carnauba wax, paraffin wax, white wax, yellow wax, or other suitable pharmaceutical wax.

44. (Previously Presented) The water-soluble or swellaable polymer of claim 42, wherein said polymer is present in the insoluble wax layer at a concentration from 0.05% to 10% by weight.

45. (Original) The water-soluble or swellaable polymer of claim 42, wherein said water-soluble or water-swellaable polymer is tragacanth, polyvinyl, pyrrolidone, polyvinyl alcohol, cross-linked polyacrylic acid, polyethylene glycol, a cellulose polymer derivative, or other suitable pharmaceutical polymer that is water-soluble or water-swellaable.

46. (Previously Presented) The wax-film composite of claim 35, wherein the molecule of interest is contained in and released from either the pH-sensitive mucoadhesive layer or the water-insoluble wax layer.

47. (Previously Presented) The wax-film composite of claim 35, wherein the molecule of interest comprises an active pharmaceutical compound such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistimine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migrane, anti-fungal, a sweetner, a flavoring agent, a diagnostic agent, or a combination thereof.

48. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is amlexanox.

49. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is triclosan.

50. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.

51. (Previously Presented) The wax-film composite of claim 35, wherein the molecule of interest is a peptide or protein.

52. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.

53. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is hirudin or hirudin complexed with a substance of opposite charge.

54. (Withdrawn) The wax-film composite of claim 53, wherein said substance of opposite charge is chitosan or protamine.

55. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is plasmid DNA or plasmid DNA complexed with a substance of opposite charge such as chitosan, protamine, or a cationic lipid.

56. (Previously Presented) The wax-film composite of claim 33, wherein the wax-film composite is applied to an application site comprising: the skin, mouth, vagina, nasal cavity, or other accessible mucosal site.

57. (Previously Presented) The wax-film composite of claim 56, wherein the wax-film composite adheres to the application site for at least one hour.

58-62. (Canceled)